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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,267	12/21/2001	Dennis Stein Everhart	16,540	3116

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EXAMINER	
STEPHENS, JACQUELINE F	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/027,267	EVERHART ET AL.	
	Examiner	Art Unit	
	Jacqueline F Stephens	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,12,16,18,21,22,33-43,45,47-52,54,55,59,62,63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 2,4-11,13-15,17,19,20,23-32,44,46,53,56-58,60 and 61.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 11/16/04 have been fully considered but they are not persuasive. In response to applicant's argument that Lucas is not discloses as being configured for partial disposition within the vestibule of a wearer, and does not have an application region for projection within the vestibule, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

2. In response to applicant's argument that Harrison is not discloses as being configured for partial disposition within the vestibule of a wearer, and does not have an application region for projection within the vestibule and the argument that Harrison does not disclose a mucoadhesive adapted to enhance the contact between the absorbent article and non-cornified epithelium of a wearer, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it

meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

With respect to the Harrison reference and claims 39 and 40, applicant further argues the creams, ointments, etc. referenced by the examiner as being taught by Harrison col. 13, lines 34-60 are not configured for use with an absorbent device. However, Harrison at col. 10, lines 12-14 teaches various delivery components and delivery devices, one of which is a tampon (Abstract). Harrison further teaches any form of drug delivery system to effectively deliver the treatment agent is within the scope of the invention (col. 7, lines 9-20).

3. In response to applicant's argument that Goldfarb is not discloses as being configured for partial disposition within the vestibule of a wearer, and does not have an application region for projection within the vestibule and that Goldfarb teaches a preferred type of feminine napkin of the construction shown in Figure 1, which comprises an absorbent portion designated generally as having a shape generally approximating the shape of the exterior surface of the female pubic area, applicant is also directed to Figure 5, where Goldfarb teaches an interlabial shape, which is capable of partial disposition within the vestibule of a wearer. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from

the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

Applicant further argues Goldfarb does not disclose therapeutic agents. However, applicant is directed to col. 3, lines 1-2 of Goldfarb, which teaches the chemical agents are used to combat infection, which acts in a manner of a therapeutic agent.

4. In response to applicant's argument that there is no suggestion to combine the references of Lucas and Bowie, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the examiner has relied on Bowie for a teaching of the use of ligand to target proteins that may be associated with a condition or disease. It is within the level of ordinary skill in the art to modify the preparation of Lucas to include a ligand to target proteins as taught in Bowie.

5. In response to applicant's argument that there is no suggestion to combine the references of Goldfarb and Karami, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Regarding the arguments about the Goldfarb reference, see paragraph 3 above. In the case of the combination of Goldfarb in view of Karami, applicant argues the examiner has not established whether the combined references would have a reasonable likelihood of success and cited In re Dow Chemical, 837 F.2d 469, 473, 5, U.S.P.Q. 2d 1529, 1531 (Fed. Cir. 1988). The discussion of reasonable likelihood of success is directed at a applications which contain claims to species or a subgenus of chemical compositions and rejections under 35 U.S.C. 103 based upon a single prior art references or additional art references, see MPEP 2144.08. In this case, the examiner is not relying on the references to reject the chemical composition of the present application, but to reject the method of treating a structure formed from a hydrophobic polymer. Goldfarb teaches a hydrophilic porous nonwoven. The examiner has relied on Karami to teach the deficiency in Goldfarb, a hydrophobic porous nonwoven, for the benefit of reducing rewet.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 12, 16, 21, 34, 35, 42, 47, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Lucas AU 199941153.

As to claims 1 and 42, Lucas discloses a tampon and method for producing a tampon comprising a fluid-absorbent body and a therapeutic agent located within an application region of the tampon (page 3, lines 18-23 and Figures 1 and 2).

As to claims 12 and 16, Lucas discloses the therapeutic agent is a powder, which is also a solid (page 2, lines 12-14).

As to claim 21, Lucas discloses the therapeutic agent is capable of treating dysmenorrhea (page 4, lines 7-10).

As to claims 34 and 47, Lucas discloses the therapeutic agent is applied to the surface of the tampon body (page 3, lines 18-23 and Figures 1 and 2).

As to claim 35, Lucas discloses the therapeutic agent is applied to the surface of the tampon body. The limitation of the agent being applied before the body is constructed is directed to a process of making the article. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its

method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). MPEP 2113.

As to claim 63, Lucas discloses a tampon and method for producing a tampon comprising a fluid-absorbent body and a therapeutic agent located within an application region of the tampon (page 3, lines 18-23; page 4, lines 4-5; and Figures 1 and 2).

8. Claims 1, 21, 22, 39, 40, 42, 43, 55, and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Harrison et al. USPN 6086909.

As to claims 1, 42, and 55, Harrison discloses a tampon and method for producing a tampon comprising a fluid-absorbent body 24 and a therapeutic agent 28 located within an application region of the tampon (Figure 4).

As to claims 21, 39, and 40, see Abstract and col. 13, lines 34-60.

As to claim 22, Harrison discloses the claimed therapeutic agents (col. 4, lines 43-59).

As to claims 43 and 62, Harrison discloses a mucoadhesive (col. 2, lines 60-63).

9. Claims 1, 3, 16, 18, 36-39, 41, 42, 45, 48-51, 52, 55, and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldfarb et al. USPN 3490454.

As to claims 1, 3, 18, 38, 42, 45, 51, 52, and 55, Goldfarb discloses a catamenial product and method for producing the product, which is capable of being partially positioned within the vestibule of a wearer and contacting the non-cornified epithelium. Goldfarb discloses a tampon product col. 2, lines comprising a fluid-absorbent body and means for carrying a formulation including a therapeutic agent (col. 2, lines 16-21; col. 3, lines 4-10; col. 4, lines 8-14).

As to claims 36 and 49, Goldfarb discloses the agent is located on an open or a gauze nonwoven, either of which is essentially an apertured web (col. 3, lines 53-54 and col. 4, lines 8-14).

As to claim 37, Goldfarb discloses the therapeutic agent is applied to creped tissue, which is well known in the art as a biodegradable material (col. 3, lines 34-44).

As to claim 39, Goldfarb discloses the therapeutic agent comprises a hydrogel (col. 6, lines 45-75).

As to claim 41, Goldfarb discloses the therapeutic agent comprises a polymeric material (col. 8, lines 8-38).

As to claims 48 and 50, Goldfarb discloses the agent is applied to various layers and between layers of the absorbent product (col. 3, lines 34-44 and col. 4, lines 8-10). Therefore, the agent is applied before the body is completed.

As to claim 59, Goldfarb discloses delivery of the therapeutic agent is affected by melting a solid (col. 7, lines 1-8).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lucas in view of Bowie et al. USPN 5585277. Lucas discloses the present invention substantially as claimed. However, Lucas does not disclose a ligand as part of the formulation. Bowie discloses ligands can be used therapeutically to bind a target protein associated with a condition or disease, preventing or treating a condition or disease, regulate physiological function, or serve as a lead compound for identification of a therapeutically useful compound (col. 1, lines 51-60). It would have been obvious

to one having ordinary skill in the art to modify the therapeutic agent of Lucas with a ligand for the benefits disclosed in Bowie.

13. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldfarb USPN 3490454 in view of Karami et al. USPN 4726976.

As to claim 54, Goldfarb discloses a catamenial product and method for producing the product, which is capable of being partially positioned within the vestibule of a wearer (Goldfarb discloses a tampon product col. 2, lines comprising a fluid-absorbent body and means for carrying a formulation including a therapeutic agent (col. 2, lines 16-21; col. 3, lines 4-10; col. 4, lines 8-14). Goldfarb discloses the agent is located on a porous nonwoven (col. 3, lines 53-54 and col. 4, lines 8-14). However, Goldfarb does not disclose the nonwoven is a hydrophobic polymer. Karami discloses a hydrophobic coversheet for the benefit of reducing rewet (col. 6, lines 33-53). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Goldfarb with a hydrophobic cover layer for the benefits disclosed in Karami.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

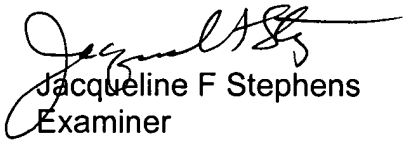
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline F Stephens whose telephone number is (571) 272-4937. The examiner can normally be reached on Monday-Friday 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Schwartz can be reached on (571)272-4390. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jacqueline F Stephens
Examiner
Art Unit 3761

February 4, 2005